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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,276	04/15/2000	GLENN F. SPAULDING	010-US-002	9303
29664	7590	05/06/2004	EXAMINER	
THE LAW OFFICES OF COE F. MILES, P.C. 15150 MIDDLEBROOK DRIVE HOUSTON, TX 77058			GABEL, GAILENE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/550,276	Applicant(s) SPAULDING, GLENN F.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,10,11,13-31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,10,11,13-31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>attached hereto</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Prosecution Reopened

1. In view of the Appeal Brief filed on 1/26/04, PROSECUTION IS HEREBY REOPENED. A non-final office action is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim status

2. Claims 1-4, 10, 11, 13-31, and 33-34 are pending and remain under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 3-4, 10, 11, 13-18, 22, 24-31, and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) in view of Walters (US 6,135,940), is hereby, withdrawn.

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4. The rejection of claims 1, 4, 10, 13-18, 22, 26-29, 31, and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), is hereby, withdrawn.

5. The rejection of claims 19-20 and 23 under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Surmodics, Inc., is hereby, withdrawn.

6. The rejection of claims 2 and 21 under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Saralegui et al. (US 5,439,645), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 10, 11, 13-31, and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards.

Claim 1, line 4, is vague and indefinite in reciting, "a light source adapted to illuminate" because it is unclear how the light source has been modified, i.e. adapted, so as to be able to illuminate. If Applicant intends that there is no adaptation or modification made to the light source so as to function differentially from any other light

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source, in illuminating the transparent cylinder, then Applicant should recite, "a light source that illuminates ..." or "a light source for illuminating ...".

Claim 1, line 6 is vague and indefinite in reciting, "a detector adapted to detect" because it is unclear how the detector has been modified, i.e. adapted, so as to be able to detect. If Applicant intends that there is no adaptation or modification made to the detector so as to function differentially from any other cytometer detector, in detecting a light signal, then Applicant should recite, "a detector that detects ..." or "a detector for detecting ...".

Same analogous comments and problems in claim 1 apply to claim 2 in reciting, "a bar code label adapted to be interrogated".

Same analogous comments and problems in claim 1 apply to claim 10 in reciting, "a rotating means adapted to rotate".

Same analogous comments and problems in claim 1 apply to claim 10 in reciting, "a light source adapted to illuminate".

Same analogous comments and problems in claim 1 apply to claim 11 in reciting, "a rotating means further adapted to sequentially rotate". See also claims 12 and 13.

Same analogous comments and problems in claim 1 apply to claim 13 in reciting, "a cap adapted to seal the open end".

Same analogous comments and problems in claim 1 apply to claim 23 in reciting, "a light emitting diode is adapted to emit".

Same analogous comments and problems in claim 1 apply to claim 26 in reciting, "light source adapted to illuminate".

Same analogous comments and problems in claim 1 apply to claim 27 in reciting, "light sources are adapted to emit".

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are drawn to a cytometer having a rotating means that rotates a transparent cylinder, a light source that illuminates the transparent cylinder while it rotates, a detector that detects light signal from the transparent cylinder while it rotates, a determining means that determines at least one cytometric characteristic of the sample disposed in the sample, and a movement means for moving the transparent cylinder, the light source, and the detector in a longitudinal axis relative to one another. "Cytometric characteristics" as recited in the claims encompasses a broad scope which includes information that is incorporated into a barcode label. In the hospital setting, barcode labels are used in identifying blood collected from patients and include information such as patient's name, social security number, age, blood type, i.e. B positive which describes a presence of B and Rh antigens in the blood cells of the patient, and diagnosis, i.e. acute myelocytic leukemia, which provides information that a patient's white blood cell count is high and have cytometric characteristics that includes

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large granular young myelocytic and blast cells, or sickle cell anemia which provides information that some of patient's red blood cells are characteristically sickled or S-shaped. Accordingly,

8. Claims 1, 2, 10, 11, 21, 22, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishina et al. (US Patent 5,582,795).

Nishina et al. disclose a hold-transfer system or apparatus for use in analyzing fluids such as blood and medicines (see column 1, lines 6-9). The apparatus comprises a rotating means (stepper motor) which receives and rotates transparent cylinders (test tubes) about the longitudinal axis of the transparent cylinder. Transparent guards are installed for protection of transparent cylinders. The apparatus has a light source such as laser or light emitting diode (LED) which illuminates a portion of the transparent cylinder (barcode) while the transparent cylinder is being rotated. The apparatus further comprises a detector and determining means (automatic scanning type barcode reader) which detects light signal provided by the light source and reflected from the barcode while the transparent cylinder is being rotated. The barcode reader determines cytometric characteristics of a sample disposed in the transparent cylinder (see column 3, line 45 to column 4, lines 19, and column 5, lines 4-20). The apparatus also includes a movements means (first and second motors) for moving the transparent cylinder, the light source and barcode reader along a longitudinal axis relative to one another (see column 3).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24, 25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Milch (US Patent 5,352,879).

Nishina et al. has been discussed supra. Nishina et al. is silent in teaching that a detector (such as a barcode reader) comprises an analog to digital converter, a photomultiplier tube, and a processing means. (see claims 4 and 5 of Milch et al.)

Milch discloses a detector means (barcode reader) that reads optically encoded information. The detector means comprises an analog to digital converter, a photomultiplier tube (two photodetectors), and processing means (control means or CPU) (see claims 4 and 5 of Milch et al.).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the analog to digital converter, photomultiplier tube, and processing means as taught by Milch into the barcode reader of Nishina because digital converters, photomultiplier tubes, and processing means constitute obvious features which are routinely known in the art as being part of a barcode reader.

10. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Izumi (US Patent 5,126,554).

Nishina et al has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the detector comprises a charge-coupled device (CCD).

Izumi discloses a detector (barcode reader) for use in reading barcode symbols. According to Izumi, the detector comprises a CCD. (See claim 3 of Izumi).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the CCD as taught by Izumi into the barcode reader of Nishina because CCDs constitute an obvious feature which is routinely known in the art as being part of a barcode reader.

11. Claims 3, 13-18, 26-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US 6,254,834).

Nishina et al has been discussed supra. Nishina et al. differ from the instant invention in failing to disclose that the transparent cylinder (which has a closed end and an open end) includes a cell guide member and has organic photoreceptor and standards affixed thereon. Nishina et al. further differ in failing to disclose that the apparatus has more than one light source.

Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms such as bacteria, virus, mycoplasma, or yeast cells in a sample contained in a transparent cylinder (centrifuge tube) (see column 10, lines 22-45). The transparent cylinder has an open end (upper region), a middle cell guide member, and a

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closed end (lower region) with successively smaller diameters (see columns 4-5). The open end is for receiving a sample which can be plugged with a sealing cap and the lower end is a tubular microbanding region for isopycnically banding all the infectious particles or cells in the presence of a fluorescent dye or a combination of fluorescent dyes. Anderson et al. disclose that the inner surface of the cylinder can be modified by treatment with non-absorptive material (see column 5). Anderson et al. also teach affixing standards into the transparent cylinder (see Example). Anderson et al. provide use of the apparatus in combination with one or more light sources emitting at different wavelengths and detection systems, i.e. diffraction grating (see column 7, lines 32-41 and column 10, lines 8-21 and 46-67). The optical signal detected from the microbanding is processed in a processing means (computer).

It would have been obvious to incorporate a cell guide member having organic photoreceptor and standards affixed thereon as taught by Anderson into the apparatus of Nishina because Nishina specifically taught that the that adapters upon which the transparent cylinders are disposed can come in various shapes to accommodate for any change in shape or configuration of a transparent cylinder (see column 6, lines 1-14), such as for example those that have incorporated thereto, cell guides having successively smaller diameter towards the lower end of the transparent cylinder such as taught by Anderson.

12. Claims 4, 19, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishina et al. (US Patent 5,582,795) in view of Anderson et al. (US

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6,254,834) as applied to claims 13-18, 26-28, and 31 above, and further in view of Surmodics, Inc..

Nishina et al. and Anderson et al. have been discussed supra. Nishina et al. and Anderson et al. differ from the instant invention in failing to disclose dibromo anthanthrone which is an organic photoreceptor material activated by a wavelength of approximately 300 nm to 100 nm.

Applicant, by way of disclosure at page 5, lines 17-22, admits that incorporation of photo cross-linking agents into the inner wall of cylinders, is known and used commercially by Surmodics, Inc. These photo-crosslinking agents include organic photoreceptor materials optimized for 300 nm - 2000 nm such as dibromo anthanthrone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immobilized reagents in the transparent cylinders taught by Anderson used in the apparatus of Nishina to include or otherwise substitute the photoreceptor materials, i.e. chromogenic materials and luminescent materials, with dibromo anthanthrone, because SurModics specifically taught its application and suitability on inner walls of cylinders such as those used by Anderson for application in the device of Anderson. Further, the parameters set forth in claims 19 and 23 wherein "(the photoreceptor material) is activated by a wavelength of approximately 300 nm - 100 nm", constitute result effective variables which Surmodics, Inc. has shown may be obtained by optimization procedures. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in

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the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 19 and 23 are for any particular purpose or solve any stated problem and the prior art teaches that photoreceptor materials often vary according to specific application or purpose or the sample being analyzed, the various detection materials and parametric requirements appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for dibromo anthanthrone as disclosed by the prior art by normal optimization procedures.

Response to Arguments

13. Applicant's arguments with respect to claims 1-4, 10, 11, 13-31, and 33-34 have been considered but are moot in view of the new grounds of rejection.

14. Applicant's argument filed 1/26/04 with regards to 35 USC 112, second paragraph rejection has been fully considered but is not persuasive.

A) Applicant argues that the term "adapted to" should be acceptable in light of the specification; thus, it is clear what is intended by the term "adapted to" if read in light of the specification.

In response, there appears to be no specific or figurative "modification" or "adaptation" described in the specification to encompass or delimit the structures, i.e. light source or detector, that are recited as being adapted to illuminate or detect differentially. Accordingly, this rejection has been maintained.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
April 29, 2004 *gg*

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05/03/04